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July 31, 2009

Clerk of the Panel
Judicial Panel on Multidistrict Litigation
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E.
Room G-255, North Lobby
Washington, DC 20002-8004

Subject: In re Hydroxycut Sales Practices Litigation
MDL Docket No. 2087

Dear Sir/Madam:

This office, along with Jacobson Schrinsky & Houck, represents Plaintiffs Marques Park and Dawn Parke with regard to the above-referenced matter. Enclosed please find an original and four copies Plaintiffs Marques Parke and Dawn Parke's Response to Plaintiffs Cody Coleman, Randall Scott Shortridge, Kim Ann Walden, Nicholas Torres, Andrew Rossi, and Courtney J. Walker's Joint Motion for Coordination and Transfer Pursuant to 28 U.S.C. §1407.

Thank you for your attention to this matter. Should you have any questions, please feel free to contact me.

Yours for clearer communications,

Kathi Eastham

Kathi Eastham, Legal Assistant

/ke

Enclosures

cc: All counsel on Certificate of Service

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: HYDROXYCUT SALES PRACTICES LITIGATION	MDL No. 2087
In re: HYDROXYCUT PRODUCT LIABILITY LITIGATION	

PLAINTIFFS MARQUES PARKE AND DAWN PARKE'S RESPONSE TO PLAINTIFFS CODY COLEMAN, RANDALL SCOTT SHORTRIDGE, KIM ANN WALDEN, NICHOLAS TORRES, ANDREW ROSSI, AND COURTNEY J. WALKER'S JOINT MOTION FOR COORDINATION AND TRANSFER PURSUANT TO 28 U.S.C. §1407

I. INTRODUCTION

Plaintiffs, Marques Parke and Dawn Parke ("Movants" or "Plaintiffs") jointly submit this memorandum of law in support of the application of an MDL but in opposition to the choice of San Diego, and instead to: (a) create this MDL in the Southern District of New York; and (b) coordinate the actions for pretrial proceedings pursuant to 28 U.S.C. §1407(a). The actions at issue satisfy the statutory prerequisites for transfer and coordination as (1) "they involve one or more common questions of fact" being substantially similar actions filed within a short time of each other in districts across the country; (2) transfer and coordination "will promote the just and efficient conduct of [the] actions" by ensuring centralized oversight of pretrial proceedings in what are likely to be highly complex and document-intensive actions, and so minimize waste and inefficiency in the conduct of discovery. *Id.*

The various Hydroxycut cases not pending in district courts across the country allege defendants manufactured, marketed and sold dangerous and/or ineffective weight-loss

supplement products in violation of product liability common law and state consumer protection statutes (the "Hydroxycut Cases").

The *Coleman et al* Plaintiffs advocate a transfer of the MDL to the Southern District of California. We agree with all of the arguments they posit regarding consolidation of the cases now pending in district courts across the country. There are indeed ample reasons to consolidate these cases. However, Plaintiffs disagree that the Southern District of California is the best choice for transfer of venue. For the numerous reasons explained *infra* Plaintiffs move to transfer these actions to the Southern District of New York.

I. ARGUMENT

A. These Actions are Appropriate for Transfer and Coordination Pursuant to §1407

The Panel may transfer and coordinate two or more civil cases for pretrial proceedings upon a determination that the cases "involv[e] one or more common questions of fact," transfer and coordination would further "the convenience of parties and the witnesses," and transfer and coordination will "promote the just and efficient conduct of [the] actions." 28 U.S.C. §1407(a). As set forth herein, the pending cases easily meet these criteria and should be transferred and coordinated for pretrial proceedings.

B. The Panel Should Transfer These Actions to the Southern District of New York

The Panel's determination of the appropriate venue in which to coordinate the pretrial proceedings in these related actions is similarly guided by §1407. Following this standard in the instant situation, the Southern District of New York emerges as superior to the other districts in which related cases have been filed because it possesses a significant nexus to this litigation and best promotes and serves the convenience of the parties and witnesses and the just and efficient conduct of the actions. *See* U.S.C. §1407(a).

1. The Southern District of New York Is an Appropriate Forum for the Hydroxycut Cases

The *Parke* complaint, while filed in the Western District of Wisconsin, we believe is best served in the Southern District of New York for the reasons set forth in the Jack Levy and Elena Levy response to the joint motion for coordination and transfer. Moreover, at least one other case, the *Robertson v. Iovate Health Sciences* (09-cv-9334) case is also pending in the S.D.N.Y. The *Parke* case alleged that the defendant proximately caused serious personal injury, to-wit acute hepatitis with submassive necrosis of the liver and jaundice, by selling a dangerous and defective product without warnings of the product's risks and advertising and marketing their Hydroxycut-branded products containing major misrepresentations and omissions concerning safety. The *Coleman* Plaintiffs advocate transfer to San Diego based on coordinating the "earliest filed" actions. *See In re Refined Petroleum Prods. Antitrust Litig.*, 528 F. Supp. 2d 1365, 1367 (J.P.M.L. 2007). However, this argument is unpersuasive as these class actions "assert consumer fraud and false advertising claims." Whether an action is the earliest one filed is irrelevant when it will not "eliminate duplicative discovery; prevent inconsistent pretrial rulings… and conserve the resources of the parties…" *In re Refined Petroleum Prods. Antitrust Litig.*, 528 F.Supp. at 1366.

With all due respect to the Coleman consumer class claims, this product was removed from the market for serious safety reasons and the persons most affected are those who suffered severe injury, not a consumer who used the product and is fine, but seeks a refund. The gravamen of the consumer fraud class action is certainly less compelling, especially when dealing with a defendant that is likely to have insufficient assets and insurance, based upon the prior experience with its predecessor in the stunningly similar *In Re: Ephedra* litigation. At most, the consumer

fraud and false advertising class actions should be regarded as incidental cases and should not be the principal claims dictating the litigation.

In light of the *Levy* and *Robertson* filing, both of which are pending in the Southern District of New York, and in light of the fact that both suffered serious injuries, we believe this litigation is better suited in that district.

Judicial economy should inform the Panel's analysis of transfer and consolidation. *Cirulli v. Bausch & Lomb*, No. 08-4579, 2009 WL 545572, at *3. For example, a compelling factor for such analysis is the factual similarities of the different cases. *Id.* Given the gravity of the injuries suffered by Levy and other personal injury plaintiffs, the judicial economy factor for deciding consolidation and transfer of venue should be based in large part on the type of pre-trial discovery necessary for complex personal injury product liability cases. *See In re Refined*, 528 F.Supp. at 1366. Moreover, Levy's injuries align with the FDA's basis for withdrawal. Just because California counsel caption their memorandum of law as "In re Hydroxycut Sales and Practices Litigation," does not mean that their consumer fraud class action should trump the products liability actions of those victims severely injured from using Hydroxycut products.

2. Transfer to the Southern District of New York Serves the Interests of the Litigants

The Southern District of New York courthouse in Manhattan is a more convenient location for the parties. *In re Aftermarket Filters Antitrust Litig.*, 572 F.Supp. 2d 1373, 1374 (J.P.M.L. 2008) ("[A]ctions are already pending in this district before one judge, and plaintiffs in numerous actions pending in this district and elsewhere support the Northern District of Illinois as their first or second choice for transferee district. Considerations of convenience and accessibility also favor the Northern District of Illinois.") While San Diego is a major city, New York is more convenient. Not only is New York served by all major airlines at its *three* airports,

it is conveniently located for transit by train, in the heavily populated northeast corridor, it is centrally located with a plethora of hotels, and it is in the region of the country from which defendants and their affiliates conduct business.

The North East Coast, not the West Coast, is the region where Iovate and its affiliates, the manufacturers of Hydroxycut, are located. While Iovate is a Canadian corporation, Iovate's United States headquarters is Blasdell, New York. Vitaquest, a contract manufacturer of Hydroxycut, is a New Jersey corporation, located in West Caldwell, New Jersey, across the river from Manhattan and the Southern District of New York. Defendant GNC is also a North East Coast corporation. GNC is headquartered in Pennsylvania, registered in New York County, and incorporated in Delaware. Additionally, GNC Franchising, LLC regularly does business in the State and County of New York and is a business entity of Pennsylvania. GN OLDCO Corp, is a Pennsylvania business entity as is General Nutrition Corporation. GNCI OLDCO, Inc. is a Delaware business entity and regularly does business in the state of New York. Clearly none of these defendants is domiciled anywhere near California.

New York is also the location from which the FDA will be monitoring the recall of Iovate's defective Hydroxycut product-line. *See* Exhibit A in which the Director of the FDA Center for Food Safety and Applied Nutrition, Stephen F. Sundlof, writes to Iovate's Terry Begley on April 30, 2009, stating "The New York District Office [of the FDA] will be monitoring the recall. The New York District Recall Coordinator is Maria Caride. She can be contacted at (718) 662-5447." *Id.*

Considering the previous nefarious conduct of defendants in the earlier Hydroxycut lines of cases, where defendants lacked sufficient assets to compensate injured victims, and instead filed for bankruptcy, and had its new entity reformulate yet another defective and dangerous product,

transfer to the Southern District of New York is appropriate where defendants will more easily be monitored.

3. Transfer to the Southern District of New York Before the Judge Who Supervised the related Ephedra MDL Would Best Promote the Just and Efficient Conduct of the Actions

Transfer of the related proceedings to the Southern District of New York would further the interests of the just and efficient conduct of the actions. The Southern District of New York is well-qualified to handle cases of the size and complexity of the instant actions.

The *In Re: Ephedra* MDL that is largely resolved, but still partially pending before The Honorable Judge Rakoff involves strikingly similar scientific causation issues, and overlapping parties. It is submitted that given Judge Rakoff's extraordinary familiarity on these key issues, having held extensive *Daubert* hearings in *In re Ephedra Prod. Liab. Litig.*, 393 F.Supp. 2d 181 (2005); *In re Ephedra Prod. Liab. Litig.*, 478 F.Supp.2d 624, 632-33 (2007); *In re Ephedra Prod. Liab. Litig.*, No. 06 Civ. 13046, 2007 WL 2947451, at *1-2., it would further judicial efficiency if he is appointed as the Judge.

Thus, the Southern District of New York is the best venue for pretrial litigation of the overlapping cases.

III. TRANSFER TO NEW YORK WOULD FACILITATE FEDERAL-STATE COORDINATION

Transfer to the Southern District of New York is desirable to enhance federal and state court coordination. *In re Zyprexa Prod. Liab. Litig.*, 489 F.Supp.2d 230, 237-38 ("Cooperation between federal and state courts has been encouraged at all states of the Zyprexa litigation."); *see, e.g., In re Zyprexa Prods. Liab. Litig.*, 467 F.Supp.2d 256, 262 (E.D.N.Y. 2006) ("Cooperation with state courts will continue to be stressed."); *In re Zyprexa Prods. Liab. Litig.*, No. MDL 1596, 2006 WL 898105, at *1 (E.D.N.Y. Apr. 16, 2006) ("Coordination and

cooperation between state and federal courts has been encouraged."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 197151 (E.D.N.Y. Jan. 30, 2006) (letter to state judges with Zyprexa cases from federal MDL judge suggesting coordination and cooperation); *In re Zyprexa Liab. Litig.*, No. MDL 1596, 2004 WL 3520248, at *4 (E.D.N.Y. Aug. 18, 2004) (directing defendant Lilly and PSCI to "confer regarding procedures for coordination of state court discovery with discovery in this MDL").

Defendant Iovate is a corporation from Blasdell, New York. There will likely be numerous parallel claims against Iovate in New York State Court by New York plaintiffs (who cannot bring suit in federal court because they lack diversity) represented by local New York counsel. Transfer of venue to the Southern District of New York is the perfect opportunity to facilitate the same cooperation between federal and state courts that expedited the Zyprexa litigation. *In re Zyprexa*, 489 F.Supp.2d 230, 237-37.

The Southern District of New York is also the best choice for venue because the Southern District is a tried and true locale for the court-appreciated device of the joint Frye/Daubert hearing. Indeed, for convenience's sake, the joint Frye/Daubert hearing for both the federal and state standards of causation is a growing trend. *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, 524 F.Supp.2d 1166, 1171; *In re Neurontin Mktg,. Sales Practices, and Prod. Liab. Litig.*, MDL No. 1629, 2009 WL 121944, at *1 n.3 (D.Mass. May 5, 2009) ("The importance of coordination of related claims in federal and state litigations has increasingly been recognized. (Manual for Complex Litigation (Fourth) §20 (2004)). The joint hearing was held in furtherance of this goal and with a view to reducing costs, delays, and duplication of effort. (*See id.* at §20.31). In addition, with the knowledge and consent of the parties, the federal and

state courts have conferred on the issues raised in the *Frye/Daubert* hearing."); *see In re Bextra and Celebrex*, 2008 N.Y. Misc. LEXIS 720, at *11; *See also* Exhibit 6.

The best way to facilitate federal and state cooperation and judicial economy, is for this Honorable Panel to consolidate and transfer Hydroxycut into an MDL venued in the Southern District of New York.

Dated: July 31, 2009

Respectfully submitted:

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By: _____
Barry Hill

News & Events

FDA Letter to Iovate Health Sciences, April 30, 2009

PDF Version (384 KB)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
College Park, MD 20740

April 30, 2009

Mr. Terry Begley
Iovate Health Sciences, Inc.
381 North Service Road, West
Oakville, Ontario Canada L6M 0H4

Dear Mr. Begley:

On March 31, 2009, the U.S. Food and Drug Administration (FDA or the Agency) informed you during a meeting of concerns that the Agency has about liver toxicity associated with the use of multiple versions of the dietary supplement Hydroxycut marketed by your firm under the Iovate and MuscleTech brand names. Based on adverse events reported to FDA, case reports in the peer-reviewed literature, and in a case series described by hepatologists to FDA, the Agency has concluded that the ingestion of the dietary supplement Hydroxycut presents a severe potentially life-threatening hazard to some users. In a telephone conversation on April 29, 2009, between [**(b)(4)**] , outside counsel for Iovate Health Sciences, Inc., and Mr. Eric Blumberg, Deputy Chief Counsel, Litigation, Office of Chief Counsel, FDA, the Agency explained our conclusions about the safety of your firm's Hydroxycut products[1] and the additional actions that the FDA expected your firm to take in response to the serious public health hazards presented by the Hydroxycut dietary supplements marketed by your firm. Following that call, your counsel advised Mr. Blumberg that the firm had agreed to recall all Hydroxycut products. The information provided by your counsel expanded the scope of your recall to include your drink mixes as well as the caplet products that your counsel had previously indicated to us that you intended to recall.

Hydroxycut products have been marketed by Iovate Health Sciences, Inc (381 North Service Rd. W., Oakville, ON L6M 0H4, Canada) and by Muscletech (Mississauga, Ontario, Canada) and distributed by Iovate Health Sciences USA,

EXHIBIT
A

Inc. (Blassdell, NY, USA) as weight control, fat-burner, and energy enhancement dietary supplements. Hydroxycut products bear the Iovate or Musletech Brand names. The products contain a variety of ingredients as well as numerous proprietary blends such as "Hydroxagen Plus," "Hydroxy Tea," "HydroxyTea CF," "Hydroxycut Proprietary Blend," "Max! Liqui-Burn," "Max! Weight-Loss Matrix," "Hydroxycut Hardcore Proprietary Blend Proxyclene," "Noreidrol Intensity focus Blend," "Lasidrate Delivery Blend," "or Yohimbacore." The products' labels declare minerals and herbs as well as extracts from *Garcinia cambogia*, *Guarana*, *gymnema sylvestre*, *Rhodiola rosea*, and *Camellia sinensis*. Prior to 2004, Hydroxycut, contained ephedra or Ma Huang as an ingredient; however, you stated to us in our meeting that by the beginning of 2004, Hydroxycut was ephedra-free. Subsequent to the removal of ephedra, Hydroxycut has undergone numerous formulation changes.

In 2002, the Center for Food Safety and Applied Nutrition's (CFSAN) adverse event reporting system, CAERS, began receiving reports of liver-related illnesses in persons who reported consuming the dietary supplement Hydroxycut capsules/caplets for periods ranging from as short as a week to two (2) months. Since the earlier formulation of Hydroxycut contained ephedra, it was generally believed that the reports of liver injury associated with the use of the product were due either to ephedra or a combination of the ingredients found in the product. However, following the removal of ephedra from Hydroxycut capsules/caplets, CFSAN continued to receive reports of liver injury associated with the use of Hydroxycut capsules/caplets. In addition, CFSAN became aware of reports of Hydroxycut-associated liver toxicity published in the peer-reviewed literature and received communications from independent hepatologists regarding cases of liver toxicity associated with the use of the Hydroxycut capsules/caplets.

Hydroxycut-associated liver toxicity reports in CAERS. To-date, 23 case reports of Hydroxycut-associated liver toxicity have been identified in CAERS for the period 2002 to the present. The number of reports, by event date, is listed below:

Year of event	Number of reports
2002	4
2003	3
2004	6
2005	0
2006	1
2007	6
2008	3

2009	0
Total	23

For cases in which gender was known, 15 (65%) were female. Ages ranged from 20 years to 51 years (median = 29 years). Sixteen cases (70%) were hospitalized. The majority of cases reported no underlying risk factors for liver disease (e.g., no history of viral hepatitis, no HIV infection, no autoimmune diseases). Although the reports vary in detail, several reports describe work-ups that ruled out infectious, autoimmune, and metabolic causes of liver disease. The severity of illness ranged from asymptomatic elevations in serum bilirubin to acute liver failure (one patient received a liver transplant in 2002, a second patient was reportedly waiting for a liver transplant in 2004) to one death. On March 24, 2009, CFSAN received information regarding the fatal case. The patient was a 20-year-old male who presented to an emergency room on January 19, 2007 in liver failure and hepatic encephalopathy. He was subsequently transferred to a liver transplant center where, in the operating room, he was found to have necrosis of both the large and small intestines. Given these findings, the procedure was aborted and the patient was returned to the intensive care unit. He died on February 12, 2007.

Reports of Hydroxycut-associated liver toxicity in the peer-reviewed literature. To our knowledge, there are four published reports in the peer-reviewed literature that describe liver disease that occurred in six persons following the consumption of Hydroxycut capsules/ caplets[2] [3] [4] [5]

The aforementioned cases are consistent with the diagnosis of idiosyncratic hepatotoxicity for a number of reasons: the temporal relationship between the consumption of Hydroxycut capsules/caplets and the development of acute liver injury in persons who had no history of known liver disease; the exclusion of other causes of liver disease following extensive work-ups; the resolution of liver injury upon discontinuation of Hydroxycut capsules/caplets; and the development of liver injury is not dose dependent. Also apparent were two distinct patterns of liver injury: cholestatic and necrotic. It is not unusual for a single herbal preparation to produce more than one type of clinicopathologic liver injury[6].

Discussions with hepatologists. In discussions in March and April 2009 with hepatologists Tse-Ling Fong, M.D. of the University of Southern California, and William Lee, M.D. of the University of Texas Southwestern Medical Center, CFSAN has become aware of these physicians' case series of patients with severe liver disease associated with the use of Hydroxycut capsules/caplets. Two cases from this series, representing additional cases to the ones reported to CFSAN, underwent liver transplantation following acute liver failure.

Serious non-hepatic adverse events identified in the CAERS database or

the literature. When the CAERS database was queried for other serious adverse events associated with Hydroxycut, cases of seizures, rhabdomyolysis,[7] and cardiovascular disorders were identified. For example, from 2004 to 2008, the CAERS database received four case reports describing consumers who experienced a seizure following ingestion of Hydroxycut. In one instance, a 26-year-old consumer increased her daily intake of Hydroxycut from 2 to 4 caplets on December 6, 2008. At 2 p.m. that day, following ingestion of the second serving of 2 caplets, the consumer felt tired and lay down. She was found by another person to be having a "seizure" (shaking and drooling). The consumer was taken to the emergency room where a physician told her to discontinue using Hydroxycut. The case report describing rhabdomyolysis involved a 23-year-old male who had been consuming Hydroxycut on and off over an eight-month period in 2002. On the day of hospital admission, he had taken 2 tablets for energy prior to working out. He reported feeling nausea, and then several hours later, he had severe shoulder pain and dark urine. He was diagnosed as having rhabdomyolysis on admission to the hospital. In addition to this CAERS report, CFSAN is aware of one case of Hydroxycut capsules/caplets-associated rhabdomyolysis reported in the peer-reviewed literature. In this report, Dehoney and Wellen described an 18-year-old male who experienced rhabdomyolysis after consuming Hydroxycut as per the product's instructions. During his overnight hospitalization, he received 6 liters of fluid before discharge.[8]

The Agency also identified 46 reports in CAERS of Hydroxycut capsules/caplets-associated cardiovascular adverse events. These events ranged in severity from palpitations to a heart attack. Nineteen of these reports were received during or after 2004, a period when Hydroxycut's formulation was believed to be free of ephedra.

Conclusion:

Three lines of evidence derived from multiple disparate sources suggest it is very likely that exposure to Hydroxycut capsules/caplets can cause idiosyncratic hepatotoxicity. First, many of the subjects described in the adverse event reports to CAERS, in the peer-reviewed literature, and in the case series described by hepatologists reported no history of liver disease or risk factors for liver disease (e.g., alcohol consumption, previous viral infection, hereditary factors, etc.) prior to experiencing liver injury following the ingestion of Hydroxycut capsules/caplets. Second, in many subjects, thorough diagnostic evaluations performed in multiple settings ruled out a number of known causes of liver disease, including viral hepatitis, autoimmune diseases, and metabolic/inherited disorders. Third, prompt resolution of liver disease occurred in a number of patients following cessation of Hydroxycut capsules/caplets ingestion. While some adverse event reports involved users who had consumed more than the daily dosage recommended on the products' labeling, if these reports were excluded from consideration, the remaining evidence demonstrates liver-related adverse effects following exposure to Hydroxycut capsules/caplets. In addition to Hydroxycut capsules/caplets-

associated liver-related adverse effects, CFSAN is aware of a number of CAERS reports that describe seizures, rhabdomyolysis, and cardiovascular signs and symptoms.

The Agency does not know which ingredient(s) of Hydroxycut formulations are responsible for producing liver toxicity. In addition, there is insufficient information to determine whether there is a dose-response effect between Hydroxycut capsules/caplets ingestion or whether its effects are cumulative over time. However, based on the totality of evidence presented above, the Agency concludes that the ingestion of the dietary supplement, Hydroxycut, presents a severe potentially life-threatening hazard to some users. Although Hydroxycut-induced hepatotoxicity has been reversible in most patients that have come to the attention of CFSAN, in certain instances acute liver failure has resulted that has required liver transplantation for survival; death occurred in one instance prior to transplantation.

While the firm believes that the lack of reported adverse events associated with the use of the Hydroxycut shot product and the drink mixes is evidence that they are safe, FDA disagrees. The reports of acute liver injury in individuals who have consumed Hydroxycut capsules/caplets represent idosyncratic reactions, meaning that the injuries have occurred as a result of conditions peculiar to the affected individuals. As such, the incidence of injuries of this nature is unpredictable and may result from peculiar metabolic interactions between one or more Hydroxycut ingredient and the host's physiologic system. There are no data to indicate that the dose or duration of use of any particular Hydroxycut ingredient, or the gender, or any other identifiable trait of a Hydroxycut user predicts the risk of an adverse event. In light of this, and because the fact that the drink mixes and 'shot' products share ingredients with products known to be associated with adverse events, and because it is unknown which ingredient(s) of Hydroxycut are responsible for producing the idiosyncratic reactions, we believe that the reasonable conclusion to be drawn is that these products present the same risks as the Hydroxycut capsules/caplets.

Given the seriousness of the hazard presented by Hydroxycut, Iovate Health Sciences, Inc. voluntarily agreed to the following:

1. To cease distribution of all existing formulations of Hydroxycut.

2. To recall from the marketplace, to the consumer/user level, all existing formulations of Hydroxycut.

As we stated above, the ingestion of the dietary supplement Hydroxycut presents a severe potentially life-threatening hazard to some users. FDA considers the recalled products to be adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 342(f)(1)(A)] (the Act) in that the dietary supplements present a significant or unreasonable risk of illness or injury under

conditions of use recommended or suggested in labeling.

The New York District Office will be monitoring the recall. The New York District Recall Coordinator is Maria Caride. She can be contacted at (718) 662-5447.

We are aware that Iovate Health Sciences, Inc. plans to reformulate the Hydroxycut product line. As discussed above, we have been unable to identify which specific ingredient or combination of ingredients can be identified as the cause of the hepatotoxicity, cardiotoxicity, seizures, or rhabdomyolysis associated with the use of the existing formulations. Under the Act, you are responsible for ensuring that a dietary supplement you market is safe within the meaning of the Act. We expect that any reformulated Hydroxycut products that contain any of the ingredients present in the existing Hydroxycut formulations would be the subject of a rigorous safety review and that a determination that the formulation(s) of the new products do not present a significant or unreasonable risk or illness or injury under the conditions of use recommended or suggested in labeling is supported by scientific evidence. We suggest that sharing the safety evaluation for the new formulation(s) with FDA will enable us to better respond to inquiries we receive concerning the safety of the new formulation(s). Further, unless each ingredient used in your new formulation(s) is affirmatively documented to have been marketed as a dietary ingredient in the United States before October 15, 1994, you may be required to submit to FDA the notification required by 21 U.S.C.§ 350b(a)(2) and 21 CFR § 190.6 at least 75 days before the reformulated product (s) are introduced into interstate commerce. If you believe you do not need to submit a 75 day notification, please provide FDA with documentation to support your determination.

Should you have any questions or comments about the contents of this letter or any aspects of your responsibilities pertaining to the marketing of your products, you may contact Dr. Vasilios Frankos at (301) 436-2375.

Sincerely yours,

/s/

Stephen F. Sundlof
Director
Center for Food Safety
and Applied Nutrition

cc: [(b)(4)]

Footnotes

[1] Hydroxycut products, for purposes of this letter, means Hydroxycut Regular

Rapid Release caplets, Hydroxycut Hardcore Liquid caplets, Hydroxycut Max Liquid caplets, Hydroxycut Caffeine-Free Rapid Release caplets, Hydroxycut Regular drink packets, Hydroxycut Hardcore drink packets (Ignition Stix), Hydroxycut Caffeine-Free drink packets, Hydroxycut Max drink packets, Hydroxycut Liquid Shots, Hydroxycut Hardcore RTDs, Hydroxycut Max Aqua Shed, Hydroxycut 24, Hydroxycut Carb Control, and Hydroxycut Natural.

[2] Stevens T, Qadri A, Zein NN. Two patients with acute liver injury associated with use of the herbal weight-loss supplement Hydroxycut. *Ann Intern Med* 2005;142:477-8.

[3] Jones FJ, Andrews AH. Acute liver injury associated with the herbal supplement Hydroxycut in a soldier deployed to Iraq. *Am J Gastroenterol* 2007;102:2357.

[4] Dara L, Hewett J, Lim JK. Hydroxycut hepatotoxicity: A case series and review of liver toxicity from herbal weight loss supplements. *World J Gastroenterol* 2008;14:6999-7004.

[5] Shim M, Saab S. Severe hepatotoxicity due to Hydroxycut: a case report. *Dig Dis Sci* 2009 Feb;54(2):406-8. Epub 2008 Jul 26.

[6] Miller SC. Safety concerns regarding ephedrine-type alkaloid-containing dietary supplements. *Mil Med* 2004;169:87-93.

[7] An acute, fulminating, potentially fatal disease of skeletal muscle that entails destruction of skeletal muscle as evidenced by myoglobinemia and myoglobinuria (Stedman's Medical Dictionary, 26th ed., Williams & Wilkins, Baltimore; 1995.

[8] Dehoney S, Wellein M. Rhabdomyolysis associated with the nutritional supplement Hydroxycut. *Am J Health Syst Pharm* 2009 Jan 15;66(2):142-86.

BEFORE THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

In Re HYDROXYCUT SALES PRACTICES LITIGATION	)	MDL No. 2087
In Re: HYDROXYCUT PRODUCTS LIABILITY LITIGATION	)	

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Plaintiffs Marques Parke and Dawn Parke's Response To Plaintiffs Cody Coleman, Randall Scott Shortridge, Kim Ann Walden, Nicholas Torres, Andrew Rossi, And Courtney J. Walker's Joint Motion For Coordination And Transfer Pursuant To 28 U.S.C. §1407 was served by First Class Mail on July 31, 2009, to the following:

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Middle District of Alabama
Ms. Debra P. Hackett
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Northern District of California
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Courthouse, 16th Floor
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400 North Miami Avenue
Miami, FL 33128

Clerk of the Court
Northern District of Illinois
Everett McKinley Dirksen
United States Courthouse, 20th Fl.
219 South Dearborn Street
Chicago, IL 60604

Clerk of the Court
Eastern District of Louisiana
C-151 Hale Boggs Federal Bldg.
United States Courthouse
500 Poydras Street
New Orleans, LA 70130

Clerk of the Court
District of Massachusetts
John Joseph Moakley United States
Courthouse, Suite 2300
One Courthouse Way
Boston, MA 02210-3002

Clerk of the Court
Eastern District of Michigan
Theodore Levin United States
Courthouse, 5th Floor
231 West Lafayette Boulevard
Detroit, MI 48226

Clerk of the Court
District of New Jersey
4015 Martin Luther King, Jr.
Federal Building and US Courthouse
50 Walnut Street
Newark, NJ 07102

Clerk of the Court
Western District of Pennsylvania
3110 United States Post Office
and Courthouse
700 Grant Street
Pittsburgh, PA 15219-1906

Clerk of the Court
Middle District of Tennessee
800 Estes Kefauver Federal Bldg.
and United States Courthouse
801 Broadway
Nashville, TN 37203-3816

Clerk of the Court
Western District of Texas
L100 United States Courthouse
111 East Broadway Street
Del Rio, TX 78840

I further certify that a copy of the foregoing Plaintiffs Marques Parke and Dawn Parke's Response To Plaintiffs Cody Coleman, Randall Scott Shortridge, Kim Ann Walden, Nicholas Torres, Andrew Rossi, And Courtney J. Walker's Joint Motion For Coordination And Transfer Pursuant To 28 U.S.C. §1407 was served by First Class Mail on July 31, 2009, to the following counsel and/or parties:

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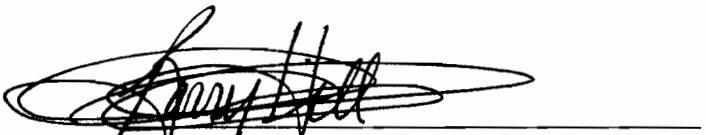

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